510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: __063407_____.

Submitter:

Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

Tel: +86 755 2658 2888

Fax: +86 755 2658 2680

- **Contact Person:**

Li Dongling
Shenzhen Mindray Bio-medical Electronics Co., LTD
Mindray Building, Keji 12th Road South, Hi-tech Industrial Park, Nanshan, Shenzhen, 518057, P. R. China

- **Date Prepared:**

Oct. 20, 2006

Name of the device:

- **Trade/Proprietary Name:** BC-3200 Auto Hematology Analyzer
- **Common Name:** Automated Differential Cell Counter
- **Classification**

21 CFR§864.5220 Automated Differential Cell Counter Class II

Legally Marketed Predicate Device:

K#990352, COULTER® A^{C}·T diff 2™ Analyzer, Coulter Corporation.

Description:

The BC-3200 Auto Hematology Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for In Vitro Diagnostic Use in clinical laboratories. It is only to be used by trained medical professionals to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies. The analyzer provides analysis results of 16 parameters (listed below) of human blood and three histograms.

Parameter	Abbreviation
White Blood Cell or leukocyte	WBC
Lymphocyte	Lymph#
Mid-sized cell	Mid#
Granulocyte	Gran#
Lymphocyte percentage	Lymph%
Mid-sized cell percentage	Mid%
Granulocyte percentage	Gran%
Red Blood Cell or erythrocyte	RBC
Hemoglobin Concentration	HGB
Mean Corpuscular (erythrocyte) Volume	MCV
Mean Cell (erythrocyte) Hemoglobin	MCH
Mean Cell (erythrocyte) Hemoglobin Concentration	MCHC
Red Blood Cell (erythrocyte) Distribution Width	RDW
Hematocrit	HCT
Platelet	PLT
Mean Platelet Volume	MPV
White Blood Cell Histogram	WBC Histogram
Red Blood Cell Histogram	RBC Histogram
Platelet Histogram	PLT Histogram

The BC-3200 Auto Hematology Analyzer system consists of the analyzer, reagents (M-30D DILUENT, M-30R RINSE, M-30CFL LYSE, M-30E E-Z CLEANSER and M-30P PROBE CLEANSER), controls (BC-3D Hematology Control), calibrator (SC-CAL PLUS Hematology Calibrator) and accessories.

Performance of the system depends on the combined integrity of all components.

The two independent measurement methods used in this analyzer are: the Coulter method for determining the WBC, RBC, and PLT data and the colorimetric method for determining the HGB.

Statement of intended Use:

The BC-3200 auto hematology analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter to be used in clinical laboratories for In Vitro Diagnostic purpose.

The intended use of BC-3200 Auto Hematology Analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.

Performance characteristics:

- **Reproducibility**

Reproducibility is stated in terms of both Standard Deviation (SD) and Coefficient of Variation (CV%).Reproducibility was deterrmined by replicate testing(n = 11)with samples of low, normal and high concentrations,three samples for each concentration.For each sample,results ofthe 2nd to 11th runs were adopted to calculate the SD and CV % . See Table 1 to Table 3 .

1	WBC ($\times10^3$ / μL)	RBC ($\times10^6$ /μL)	HGB (g/dL)	MCV (fl)	PLT ($\times10^3$ /μL)
mean	4.1	2.88	9.2	64.6	162
SD	0.07	0.04	0.1	0.40	5.06
CV(%)	1.63	1.45	0.8	0.62	3.12
2	WBC ($\times10^3$ / μL)	RBC ($\times10^6$ /μL)	HGB (g/dL)	MCV (fl)	PLT ($\times10^3$ /μL)
mean	3.2	3.02	9.3	72.9	155
SD	0.03	0.03	0.1	0.21	7.02
CV(%)	0.99	1.06	1.0	0.28	4.53
3	WBC ($\times10^3$ / μL)	RBC ($\times10^6$ /μL)	HGB (g/dL)	MCV (fl)	PLT ($\times10^3$ /μL)
mean	3.1	1.91	5.6	61.0	61
SD	0.06	0.03	0.1	0.24	5.11
CV(%)	1.84	1.76	1.1	0.39	8.39

Table 1 Imprecision , low concentration samples

1	WBC (×10^3 / μL)	RBC (×10^6 /μL)	HGB (g/dL)	MCV (fl)	PLT (×10^3 /μL)
mean	10.1	4.60	13.1	83.3	244
SD	0.12	0.03	0.09	0.38	8.05
CV(%)	1.18	0.73	0.7	0.45	3.30
2	WBC (×10^3 / μL)	RBC (×10^6 /μL)	HGB (g/dL)	MCV (fl)	PLT (×10^3 /μL)
mean	9.8	5.34	15.2	83.1	249
SD	0.10	0.04	0.12	0.27	4.86
CV(%)	0.99	0.78	0.8	0.33	1.95
3	WBC (×10^3 / μL)	RBC (×10^6 /μL)	HGB (g/dL)	MCV (fl)	PLT (×10^3 /μL)
mean	11.3	5.27	15.0	85.9	231
SD	0.13	0.04	0.06	0.21	8.53
CV(%)	1.11	0.73	0.4	0.25	3.70

Table 2 Imprecision , normal concentration samples

1	WBC (×10^3 / μL)	RBC (×10^6 /μL)	HGB (g/dL)	MCV (fl)	PLT (×10^3 /μL)
mean	16.7	6.98	22.4	112.1	419
SD	0.31	0.09	0.2	0.79	9.73
CV(%)	1.85	1.24	0.7	0.71	2.32
2	WBC (×10^3 / μL)	RBC (×10^6 /μL)	HGB (g/dL)	MCV (fl)	PLT (×10^3 /μL)
mean	25.1	6.22	18.8	/	408
SD	0.26	0.05	0.2	/	6.45
CV(%)	1.03	0.84	0.8	/	1.58
3	WBC (×10^3 / μL)	RBC (×10^6 /μL)	HGB (g/dL)	MCV (fl)	PLT (×10^3 /μL)
mean	18.5	6.09	18.0	/	495
SD	0.17	0.04	0.2	/	11.44
CV(%)	0.93	0.60	0.8	/	2.31

Table 3 Imprecision , high concentration samples

● Iner-Laboratory Precision

Two laboratories, each having one BC-3200 installed, were selected for the test. Three samples of various concentrations (respectively low, normal and high) were prepared, each with sufficient volume to run twice on both of the BC-3200s. Each BC-3200 was operated by one operator, who conducted the test from

beginning to the end. Each sample was divided into two aliquots, and the two aliquots were analyzed respectively by the two selected laboratories within the same day of preparation. Each aliquot was run twice on the BC-3200 and both runs were conducted within a short interval. No outlier was found during the test.

Based on the data acquired, repeatability variance (S_r^2), between laboratory variance (S_L^2), and reproducibility variance (S_R^2) of the following parameters, WBC, RBC, HGB, MCV , PLT, Lymph%, Mid% and Gran%, were calculated for each concentration. The inter-laboratory precision see table 4.

		Low	**Normal**	**High**
WBC （$\times 10^3$ / μL）				
Mean		2.13	8.10	20.68
Repeatability variance	S_r^2	0.0025	0.0098	0.0613
Between Laboratory variance	S_L^2	0.0000	0.0151	0.0000
Reproducibility variance	S_R^2	0.0025	0.0249	0.0613
	S_R	0.0500	0.1578	0.2476
	CV%	2.35%	1.95%	1.20%
Gran (%)				
Mean		32.53	60.98	81.30
Repeatability variance	S_r^2	1.1050	0.0221	0.0637
Between Laboratory variance	S_L^2	1.7588	0.7703	0.0932
Reproducibility variance	S_R^2	2.8638	0.7924	0.1569
	S_R	1.6923	0.8902	0.3961
	CV%	5.20%	1.46%	0.49%
Lymph (%)				
Mean		12.65	28.83	51.30
Repeatability variance	S_r^2	0.2073	0.0613	3.0439
Between Laboratory variance	S_L^2	0.0000	1.3307	6.4781

Reproducibility variance	S_R^2	0.2073	1.3920	9.5220
	S_R	0.4553	1.1798	3.0858
	CV%	3.60%	4.09%	6.02%
Mid (%)				
Mean		6.05	10.20	16.18
Repeatability variance	S_r^2	0.0490	0.0098	0.6655
Between Laboratory variance	S_L^2	0.0205	0.0751	1.3786
Reproducibility variance	S_R^2	0.0695	0.0849	2.0441
	S_R	0.2636	0.2914	1.4297
	CV%	4.36%	2.86%	8.84%
RBC ($\times 10^6$/μL)				
Mean		2.48	4.89	5.80
Repeatability variance	S_r^2	0.0004	0.0065	0.0085
Between Laboratory variance	S_L^2	0.0007	0.0013	0.0000
Reproducibility variance	S_R^2	0.0011	0.0078	0.0085
	S_R	0.0332	0.0883	0.0922
	CV%	1.34%	1.81%	1.59%
HGB (g/L)				
Mean		6.35	14.08	19.13
Repeatability variance	S_r^2	0.0000	0.0025	0.0123
Between Laboratory variance	S_L^2	0.0050	0.0601	0.0952
Reproducibility variance	S_R^2	0.0050	0.0626	0.1075
	S_R	0.0707	0.2502	0.3279
	CV%	1.11%	1.78%	1.71%
MCV (fl)				

Mean		77.28	86.73	96.33
Repeatability variance	S_r^2	0.1103	0.0123	0.0907
Between Laboratory variance	S_L^2	2.2562	1.5252	2.7160
Reproducibility variance	S_R^2	2.3665	1.5375	2.8067
	S_R	1.5383	1.2400	1.6753
	CV%	1.99%	1.43%	1.74%
PLT ($\times 10^3$ /μL)				
Mean		94.75	258.25	468.50
Repeatability variance	S_r^2	13.2453	16.2699	12.5033
Between Laboratory variance	S_L^2	14.5024	69.9901	65.7484
Reproducibility variance	S_R^2	27.7477	86.2600	78.2517
	S_R	5.2676	9.2876	8.8460
	CV%	5.56%	3.60%	1.89%

Table 4 Within-run precision and total precision

Appendix of Table 4:

WBC	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	2.2	8.1	20.5	2.15	8.2	20.75	0.07	0.14	0.35
	2.1	8.3	21						
2	2.1	8	20.6	2.1	8	20.6	0	0	0
	2.1	8	20.6						

Gran(%)	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	32.5	60.2	81.1	31.45	60.35	81.05	1.48	0.21	0.07
	30.4	60.5	81						
2	33.5	61.6	81.8	33.6	61.6	81.55	0.14	0	0.35
	33.7	61.6	81.3						

Lymph (%)	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High

1	12.8	29.9	51.7	12.75	29.65	53.3	0.07	0.35	2.26
	12.7	29.4	54.9						
2	12.1	28	50	12.55	28	49.3	0.64	0	0.99
	13	28	48.6						

Mid (%)	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	6.1	9.9	15.8	6.2	10	15.25	0.14	0.14	0.78
	6.3	10.1	14.7						
2	6.1	10.4	16.5	5.9	10.4	17.1	0.28	0	0.85
	5.7	10.4	17.7						

RBC	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	2.44	4.78	5.84	2.455	4.845	5.765	0.02	0.09	0.11
	2.47	4.91	5.69						
2	2.51	4.99	5.89	2.495	4.94	5.84	0.02	0.07	0.07
	2.48	4.89	5.79						

HGB	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	6.3	13.9	18.8	6.3	13.9	18.9	0	0	0.14
	6.3	13.9	19						
2	6.4	14.3	19.4	6.4	14.25	19.35	0	0.07	0.07
	6.4	14.2	19.3						

MCV	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	76.5	85.9	95.2	76.2	85.85	95.15	0.42	0.07	0.07
	75.9	85.8	95.1						
2	78.5	87.5	97.8	78.35	87.6	97.5	0.21	0.14	0.42
	78.2	87.7	97.2						

PLT	Form A			Form B			Form C		
Laboratory	Low	Normal	High	Low	Normal	High	Low	Normal	High
1	88	265	466	91.5	264.5	462.5	4.95	0.71	4.95
	95	264	459						
2	97	248	474	98	252	474.5	1.41	5.66	0.71
	99	256	475						

● Linearity

Linearity was determined by running diluted samples. RBC,HGB are diluted by blood plasma of the sample , while WBC and PLT are diluted by specified diluent . Concentrations from 0 to 100 % were tested , each concentration twice . The average of the two runs is taken as the result , together with the concentration , to calculate per the linear regression equation . See Table 5 to Table 8 .

Dilution（%）	Test 1	Test 2	Mean	Ideal	Error	Proportional error
100	117.1	115.9	116.50	120.01	3.51	2.9
80	99.8	100.1	99.95	96.01	-3.94	-4.1
60	73.4	72.1	72.75	72.00	-0.75	-1.0
40	47.8	48.6	48.20	48.00	-0.20	-0.4
20	23.1	23.1	23.10	23.99	0.89	3.7
10	12.1	12.0	12.05	11.99	-0.06	-0.5
5	6.0	6.2	6.10	6.00	-0.10	-1.7
2.5	3.0	2.9	2.95	2.99	0.04	1.3
1.25	1.3	1.3	1.30	1.49	0.19	12.8
0.625	0.5	0.5	0.50	0.74	0.24	32.4
0.3125	0.2	0.1	0.15	0.36	0.21	58.3
0	0	0	0.00	-0.01	-0.01	/
Slope	1.2002					
Intercept	-0.0129					

Table 5 WBC Linearity

Dilution（%）	Test 1	Test 2	Mean	Ideal	Error	Proportional error
100	8.46	8.43	8.445	8.519	0.074	0.9
80	6.91	6.86	6.885	6.819	-0.066	-1.0
60	5.12	5.17	5.145	5.119	-0.026	-0.5
40	3.42	3.46	3.440	3.419	-0.021	-0.6
20	1.71	1.69	1.700	1.719	0.019	1.1
10	0.89	0.87	0.880	0.869	-0.011	-1.3
5	0.46	0.46	0.460	0.444	-0.016	-3.6
2.5	0.21	0.22	0.215	0.232	0.017	7.3
1.25	0.10	0.13	0.115	0.125	0.010	8.0
0	0.00	0.00	0.000	0.019	0.019	/
Slope	0.0850					

Intercept	0.0191

Table 6 RBC Linearity

Dilution（%）	Test 1	Test 2	Mean	Ideal	Error	Proportional error
100	25.6	25.6	25.60	25.40	-0.20	-0.8
80	20.5	20.1	20.30	20.33	0.03	0.1
60	15.1	14.9	15.00	15.26	0.26	1.7
40	10.1	10.1	10.10	10.19	0.09	0.9
20	5.2	5.0	5.10	5.11	0.01	0.2
10	2.7	2.6	2.65	2.58	-0.07	-2.7
5	1.4	1.4	1.40	1.31	-0.09	-6.9
2.5	0.7	0.7	0.70	0.68	-0.02	-2.9
1.25	0.4	0.4	0.40	0.36	-0.04	-11.1
0	0.0	0.0	0.00	0.04	0.04	/
Slope	0.2536					
Intercept	0.0425					

Table 7 HGB Linearity

Dilution（%）	Test 1	Test 2	Mean	Ideal	Error	Proportional error
100	1014	1008	1011.0	1040.3	29.3	2.8
80	850	858	854.0	832.5	-21.5	-2.6
60	631	650	640.5	624.8	-15.7	-2.5
40	425	419	422.0	417.0	-5.0	-1.2
20	221	208	214.5	209.3	-5.2	-2.5
10	109	101	105.0	105.4	0.4	0.4
5	53	53	53.0	53.5	0.5	0.9
2.5	23	17	20.0	27.5	7.5	27.3
1.25	8	5	6.5	14.5	8.0	55.2
0	0	0	0.0	1.6	1.6	/
Slope	10.3871					
Intercept	1.5618					

Table 8 PLT Linearity

- **Carryover**

Carryover was determined by first running the high concentration sample for

three consecutive times (i1, i2, i3) and then the low concentration sample three consecutive times (j1, j2, j3), and finally calculating per the following equation:

Carryover (%) = [(j1 – j3)/ (i3-j3)]× 100%

The test was then repeated using the high level control. See Table 9 and Table 10.

Parameter	High concentration sample (whole blood)			Low concentration sample (whole blood)			Carryover %
	i1	i2	i3	j1	j2	j3	
WBC($\times10^3$ / μL)	19.7	20.4	20.0	1.9	1.9	1.9	0%
RBC($\times10^6$ /μL)	6.34	6.24	6.2	1.87	1.96	1.85	0.46%
HGB(g/dL)	25.4	25.0	24.8	3.3	3.2	3.2	0.46%
PLT($\times10^3$ /μL)	404	390	396	31	34	33	0%

Table 9 Carryover, high concentration sample

Parameter	High concentration sample (high level control)			Low concentration sample (specified diluent)			Carryover %
	i1	i2	i3	j1	j2	j3	
WBC($\times10^3$ / μL)	21.7	21.3	21.7	0.0	0.0	0.0	0%
RBC($\times10^6$ /μL)	5.88	5.79	5.79	0.00	0.00	0.00	0%
HGB(g/dL)	18.8	18.7	18.9	0.0	0.0	0.0	0%
PLT($\times10^3$ /μL)	453	438	429	0	0	0	0%

Table 10 Carryover, high level control

● Correlation

Correlation is determined by comparing the results (both CBC and DIFF) obtained by the BC-3200 to those by the Coulter A^C·T diff 2^{TM} and by comparing the DIFF results obtained by the BC-3200 to those by manual differential . See Table 11 and Table 12 .

Parameters	Sample (n)	Mean		Difference ratio (D%)	Slope (a)	Intercept (b)	Correlation coefficients
		BC-3200	A^c. T diiff 2				
WBC	103	10.4	10.3	2.4	1.0097	-0.0282	0.9994
Lymph#	98	1.9	2.1	11.8	0.9918	-0.1864	0.9890
Mid#	98	0.7	0.5	40.5	2.1022	-0.3798	0.9187
Gran#	98	6.1	6.0	3.7	0.9886	0.1460	0.9978
Lymph%	98	25.8	29.3	11.5	0.7935	2.5772	0.9751
Mid%	98	9.0	6.7	43.0	0.7569	3.8798	0.4644

Gran%	98	65.2	64.0	3.4	0.9046	7.3470	0.9707
RBC	103	4.31	4.27	1.7	0.9916	0.0702	0.9971
HGB	103	12.6	12.5	1.2	0.9951	0.0853	0.9982
HCT	103	37.6	37.2	2.2	1.0041	0.2953	0.9950
MCV	103	87.8	87.5	1.2	0.9549	4.3174	0.9824
MCH	103	29.2	29.5	1.6	0.9426	1.4345	0.9791
MCHC	103	33.3	33.7	1.8	0.7759	7.1720	0.6784
RDW	103	13.1	13.5	4.7	0.4393	7.1667	0.9569
PLT	103	226	230	8.0	0.8882	21.837	0.9961
MPV	102	8.5	8.9	4.7	0.7037	2.2287	0.9334

Table 11 Correlation to Coulter A^{C}·T diff 2^{TM}

Parameter	Samples（n）	Mean		Slope（a）	Intercept（b）	Correlation coefficient（r）
		BC-3200	Manual differential			
Lymph%	196	26.8	30.4	0.7575	3.7958	0.95
Mid%	196	9.2	9.0	0.3739	5.822	0.57
Gran%	196	64.0	60.6	0.8456	12.721	0.94

Table 12 Correlation to manual differential

● Ability to flag abnormal WBC histograms

BC-3200's ability to flag abnormal WBC histograms was determined by comparing 200 sample results obtained by the BC-3200 to those obtained by manual diferential.See Table 13.

Manual differential	BC-3200	
	Positive (39)	Negative (161)
Positive (40) Negative (160)	TP （22） FP （17）	FN （18） TN （143）
Agreement（%）	False Positive Ratio (%)	False Negative Ratio (%)
82.5	10.6	45

Table 13 Ability to flag abnormal WBC histograms

● Reference Ranges

A Normal Ranges Study was conducted to assess the Reference Ranges for the BC-3200 analyzer.Whole-blood samples were collected from 121 donors.

Normal Population Study

Parameter	Units	Sex	Mean	90%Confidence Low Limit	90%Confidence High Limit
WBC	$\times 10^3$cells /μL	M/F	6.86	3.47	10.25
RBC	$\times 10^6$cells /μL	M/F	4.56	3.54	5.58
HGB	g/ dL	M/F	13.40	10.27	16.52
HCT	%	M/F	40.12	30.98	49.26
MCV	fL	M/F	88.18	80.82	95.55
MCH	pg	M/F	29.36	26.57	32.15
MCHC	g/ dL	M/F	33.33	32.09	34.56
PLT	$\times 10^3$cells /μL	M/F	209.92	119.62	300.22
RDW	%	M/F	12.81	11.53	14.10
MPV	fL	M/F	8.47	7.07	9.87
Lymph	%	M/F	27.33	18.11	36.55
Mid	%	M/F	9.45	5.23	13.67
Gran	%	M/F	63.26	51.62	74.89

Table 14 Reference Range

Comparison of Technological Characteristics:

Compare the BC-3200 Auto Hematology Analyzer to COULTER® A^C·T diff 2^{TM} Analyzer

NO.	Feature	BC-3200 Auto Hematology Analyzer	COULTER® A^C·T diff 2^{TM} Analyzer
1	**Intended Use**	The BC-3200 auto hematology analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter for In Vitro Diagnostic Use in clinical laboratories.	The COULTER® A^C·T diff 2^{TM} Analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter For In Vitro Diagnostic Use in clinical laboratories.
2	**Sample Types**	Whole Blood Mode and Prediluted Mode	Whole blood mode and Prediluted mode
3	**Operating Modes**	Closed Vial Whole Blood mode	Open Vial Whole Blood mode and Closed Vial Whole Blood mode
4	**Throughput**	1 minute / analysis	60 seconds or less

5	**Reagents Required**	M-30D DILUENT； M-30R RINSE； M-30CFL LYSE； M-30E E-Z CLEANSER； M-30P PROBE CLEANSER	dff A^C·T Park or diff A^C·T Tain reagent park, both of which contain diluent and lytic reagent. A^C·T Rinse Shutdown Diluent
6	**Operating Rage**		
	WBC	0.0 - 299.9 ($\times10^3$/μL)	0.0-150 ($\times10^3$/μL)
	RBC	0.00 - 19.99 ($\times10^6$/μL)	0.00-8.00 ($\times10^6$/μL)
	HGB	0 – 29.9 (×g/dL)	0.00-30.0 (×g/dL)
	PLT	0 - 2999 ($\times10^3$/μL)	000-3000 ($\times10^3$/μL)
	MCV	0.0 - 249.9fL	50.0-130.0 fL
7	**Background Counts**		
	WBC	0.3×10^3 /μL or less	0.4×10^3 /μL or less
	RBC	0.03×10^6 /μL or less	0.04×10^6 /μL or less
	HGB	0.1 g/dL or less	0.2 g/dL or less
	PLT	10 × 10^3 /μL or less	7.0×10^3 /μL or less
8	**Reproducibility**		
	WBC	7.0-15.0×10^3 /μL 3.0% or less	6.0-15.0×10^3 /μL 3.0% or less
	RBC	3.50-6.00×10^6 /μL 2.5% or less	3.00-6.00×10^6 /μL 3.0% or less
	HGB	11.0-18.0 g/dL 2.0% or less	12.0-18.0 g/dL 2.0% or less
	MCV	80.0-110.0 fL 2.0% or less	80.0-100.0 fL 3.0% or less
	PLT	200-400×10^3 /μL 6.0% or less	200-500×10^3 /μL 7.0% or less
9	**Linearity**		
	WBC	0.3-99.9 ($\times10^3$/μL) ±0.3 or ±5%	0 – 99.9($\times10^3$/μL) ±0.3 or ±5%
	RBC	0.20 -7.99($\times10^6$/μL) ±0.05 or ±5%	0 – 7.0($\times10^6$/μL) ±0.05 or ±5.0%
	HGB	1.0-24.9 (g/dL) ±0.2or ±3%	0 - 25.0 (g/dL) □ ±0.2 or ±3.0%
	PLT	10-999($\times10^3$/μL) ±10 or ±10%	0 - 999 ($\times10^3$/μL) □ ±10.0 or ±10.0%

10	**Carryover**		
	WBC	0.5% or less	2.0% or less
	RBC	0.5% or less	2.0% or less
	HGB	0.5% or less	2.0% or less
	PLT	1.0% or less	2.0% or less
11	**Principles**		
	WBC	Coulter method	Coulter method
	RBC	Coulter method	Coulter method
	PLT	Coulter method	Coulter method
	HGB	Colorimetric method	Hemoglobinometry method
12	**Analysis Vessels**	Simultaneous analysis of RBC and WBC in separate analysis vessels, and using a single aperture each of WBC and RBC counting and sizing.	Simultaneous analysis of RBC and WBC in separate analysis vessels, and using a single aperture each of WBC and RBC counting and sizing.
13	**Normal Patient Ranges**	Ability to set normal patient ranges against which sample results are compared. Sample results are flagged with "H" is the result is above the normal range and "L" if below the normal range.	Ability to set normal patient ranges against which sample results are compared. Sample results are flagged with "H" is the result is above the normal range and "L" if below the normal range.
14	**Sample Processing**	Utilizes an automatic sampling, diluting and mixing device for sample processing.	Utilizes an automatic sampling, diluting and mixing device for sample processing.
15	**Quality Control**	Provides 2 QC programs: L-J Analysis and X-B Analysis.	Provides QC programs: L-J Analysis.
16	**Calibration**	Provides 2 calibration programs: manual calibration and auto calibration using commercial calibrators.	Provides 2 calibration programs: manual calibration and auto calibration using commercial calibrators.
17	**Aperture Alert**	Minimize the possibility	Minimize the possibility

		of reporting erroneous results caused by a partial or transient aperture clog or by other aperture disturbance.	of reporting erroneous results caused by a partial or transient aperture clog or by other aperture disturbance.
18	**Software**	This system is run by computer software. Ability to calculate data, store data and review results.	This system is run by computer software. Ability to calculate data, store data and review results.
19	**Recommended Controls**	BC-3D :Low, Normal and High	4C PLUS cell control: abnormal low, normal, and abnormal high.
20	**Recommended Calibrator**	SC-CAL PLUS	S-CAL calibrator
21	**Sample Volume Aspirated**	13μL of whole blood 20μL of predilute blood	18μL of whole blood 20μL of prediluted blood
22	**Parameters**	Parameters: WBC, RBC, HGB, HCT, MCV, MCH, MCHC, PLT, Lymph%, Lymph#, Mid%, Mid#, Gran%, Gran#, RDW, MPV	Parameters: WBC, RBC, Hgb, Hct, MCV, MCH, MCHC, Plt, LY%, LY#, MO%, MO#, GR%, GR#, RDW, MPV

The BC-3200 Auto Hematology Analyzer is substantially equivalent to COULTER® A^C·T diff 2™ Analyzer. The design, components, characteristic performance of the BC-3200 Auto Hematology Analyzer is similar to its predicate device. The system provides a means for count WBC, RBC, PLT and HGB for human in clinical laboratory.

The differences between the BC-3200 Auto Hematology Analyzer and COULTER® A^C·T diff 2™ Analyzer are performance value, sample volume aspirated and operating mole. These differences do not affect the safety or efficacy of the device.

Testing:

Laboratory testing was conducted to validate and verify that the BC-3200 Auto Hematology Analyzer met all design specifications and was substantially equivalent to the predicate device. The testing was performed to demonstrate compliance with the hazard analysis of the system and its

software was performed and testing was conducted to validate the systems overall operation. The BC-3200 Auto Hematology Analyzer has also been tested to assure compliance to the requirements of various published standards, including IEC61010-1, IEC61010-2-101, ISO14971, EN 13640, EN 591, EN 375, EN 980 and IEC 61326.

Clinical testing was conducted to validate and verify that the BC-3200 Auto Hematology Analyzer met all design performance characteristic and was substantially equivalent to the predicate device. The testing consisted of all performance identified in the Guidance Document issued on December 4, 2001 "Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells; Final Guidance for Industry and FDA".

Although the device is neither life supporting nor life sustaining, diagnostic information derived from the use of the device and alarms generated by the device may be critical to the proper management of the patient. So, the areas of risk for this device are the same as other devices in this class, the significant risk is misdiagnosis:

- Inadequate design of the signal processing and measurement circuitry or program can lead generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

- Inadequate design of the device's software, used to make various measurements, can lead to generation of inaccurate diagnostic data. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk unnecessarily.

Conclusion:

The conclusions drawn from clinical and laboratory testing of the BC-3200 Auto Hematology Analyzer demonstrates that the device is as safe, as effective, and performs as well as the legally marketed predicate device-COULTER® A^C·T diff 2^{TM} Analyzer.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 11 2007

Susan D. Goldstein-Falk
Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
c/o MDI Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, New York 11021

Re: k063407
Trade/Device Name: BC-3200 Auto Hematology Analyzer
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: May 31, 2007
Received: June 1, 2007

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter

will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150, or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Robert L. Becker, Jr., MD, PhD
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K063407

Device Name: BC-3200 Auto Hematology Analyzer

Indications for Use:

The BC-3200 auto hematology analyzer is a quantitative, automated hematology analyzer and leukocyte differential counter to be used in clinical laboratories for In Vitro Diagnostic purpose.

The intended use of BC-3200 Auto Hematology Analyzer is to identify the normal patient, with all normal system-generated parameters, and to flag or identify patient results that require additional studies.

Prescription Use __X__ **Over-The Counter Use** ____

(Per 21 CFR 801 Subpart D) **OR** **(21 CFR 807 Subpart C)**

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

0041

510(k) K063407